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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/627,941	Applicant(s) HENDRICKSEN ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7.25.2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 19-37, 42, 45-47, 49, 51-55 and 59-69 is/are rejected.
- 7) ☒ Claim(s) 16, 18, 38-41, 43, 44, 48, 50 and 56-58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09.03.2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7.1.05; 10.13.04; 11.18.03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The first paragraph of the first page of the specification must include updated status of the copending applications.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 7, 9, 11-15, 17, 19, 21-23, 25-31, 34-37, 42, 46, 47, 49, 51, 54, 55, 59, 60 and 62-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Zadno-Azizi et al. (US 5,954,766).

3. As to claims 1, 45, 54, 60 and 66, Zadno-Azizi teaches an apparatus that comprises a valve member 24 (see figure 1; column 2 lines 40-50) that regulates fluid flow through the flow control device, the valve having a default shape; a frame 30 (see column 3 lines 1-10) coupled to the valve member, the frame comprising a valve protector region 22 (see column 2 lines 40-50) that at least partially surrounds the valve member to maintain the default shape (see figure 1); and a retainer region 32 (see figure 2; column 3 lines 1-10) connected to the valve protector region, the retainer region being formed of a plurality of interconnected struts 34 (see figure 2; column 3 lines 1-10) configured to engage an interior wall of the bronchial passageway to retain the flow control device in a fixed location therein (see summary of invention), the retainer

region being movable from a contracted state suitable for introduction into the bronchial passageway to an expanded state suitable for engaging the interior wall of the bronchial passageway (see **column 3 lines 1-10**); and a membrane **20** (see **column 3 lines 10-25**) covering at least a portion of the retainer region, wherein at least a portion of the flow control device forms a seal with the interior wall of the bronchial passageway when the flow control device is implanted in the bronchial passageway, and wherein the membrane provides a fluid pathway from the seal to the valve member to direct fluid flowing through the bronchial passageway into the valve member (see **figures 1 and 2**).

4. As to **claim 2**, Zadno-Azizi teaches an apparatus wherein the membrane covers the entire retainer region of the frame (see **figure 3; column 3 lines 10-25**).

5. As to **claim 3**, Zadno-Azizi teaches an apparatus wherein the membrane covers the retainer region of the frame and the valve protector region of the frame (see **figure 3; column 2 lines 30-45**).

6. As to **claim 4**, Zadno-Azizi teaches an apparatus wherein the struts of the frame are arranged to form a plurality of cells, and wherein the cells are covered by the membrane (see **figures 3 and 5**).

7. As to **claim 6**, Zadno-Azizi teaches an apparatus wherein the valve member limits fluid flow in an inhalation direction and permits fluid flow in the exhalation direction (see **summary of invention**).

8. As to **claim 7**, Zadno-Azizi teaches an apparatus wherein the valve member blocks fluid flow in inhalation direction and permits fluid flow in an exhalation direction (see **summary of invention**).

9. As to **claim 9**, Zadno-Azizi teaches an apparatus wherein the valve member comprises a duckbill valve having a pair of opposed walls having edges that form opposed lips of a mouth, wherein the walls can move with respect to one another to open and close the mouth (**see figures 1 and 2**).

10. As to **claim 11**, Zadno-Azizi teaches an apparatus wherein the lips of the mouth are straight (**see figures 1 and 2**).

11. As to **claim 12**, Zadno-Azizi teaches an apparatus wherein the opposed walls have domed outer surfaces (**see figure 5**).

12. As to **claim 13**, Zadno-Azizi teaches an apparatus wherein the opposed walls have a flat outer surfaces (**see figure 3**).

13. As to **claim 14**, Zadno-Azizi teaches an apparatus wherein the flow channel is located between the lips of the valve mouth (**see figures 1 and 2**).

14. As to **claim 15**, Zadno-Azizi teaches an apparatus wherein the valve protector region comprises a tube (**see figure 3**).

15. As to **claim 17**, Zadno-Azizi teaches an apparatus wherein the tube is non-expandable (**see column 2 lines 25-40**)

16 As to **claim 19**, Zadno-Azizi teaches an apparatus wherein the valve protector is flexible (**see column 2 lines 25-40**).

17 As to **claim 21**, Zadno-Azizi teaches an apparatus wherein the valve protector and the retainer region are formed from a single piece of material (**see column 2 lines 25-40**).

18 As to **claim 22**, Zadno-Azizi teaches an apparatus wherein the single piece of material comprises a tube (**see column 2 lines 25-40**).

19. As to **claim 23**, Zadno-Azizi teaches an apparatus wherein the valve protector region and the retainer region are composed of the same material (**see column 2 lines 25-40**).
20. As to **claim 25**, Zadno-Azizi teaches an apparatus wherein the struts form a series of undulating loops in the contracted state (**see figure 2**).
21. As to **claim 26**, Zadno-Azizi teaches an apparatus wherein the undulating loops form a series of zig-zags in the expanded state (**see figure 2**).
22. As to **claim 27**, Zadno-Azizi teaches an apparatus wherein the struts form at least two connected rows of undulating loops in the contracted state, the connected rows of undulating loops forming a series of diamond-shaped cells in the expanded state (**see figure 2**).
23. As to **claim 28**, Zadno-Azizi teaches an apparatus that further comprises a plurality of linking struts connecting the valve protector region to the retainer region (**see figure 2**).
24. As to **claim 29**, Zadno-Azizi teaches an apparatus wherein the linking struts extend in a longitudinal direction from the valve protector region to the retainer region (**see figure 2**).
25. As to **claim 30**, Zadno-Azizi teaches an apparatus wherein the membrane secures the valve member to the frame (**see figure 2**).
26. As to **claim 31**, Zadno-Azizi teaches an apparatus wherein the linking struts are flexible (**see figure 2; column 3 lines 1-10**).
27. As to **claim 34**, Zadno-Azizi teaches an apparatus wherein the valve protector region has a first diameter and the retainer region has a second diameter larger than the first diameter, the linking struts extending radially outwardly from the valve protector region to the retainer region (**see figure 2**).

28. As to **claim 35**, Zadno-Azizi teaches an apparatus wherein the linking struts are curved radially outwardly from the valve protector region to the retainer region (**see figures 2 and 13**).

29. As to **claim 36**, Zadno-Azizi teaches an apparatus wherein the struts of the retainer region form a plurality of zig-zags in the expanded state, each zig-zag having a proximal point and a distal point with a strut extending therebetween, each linking strut being connected to one of the proximal points (**see figures 2 and 13**).

30. As to **claim 37**, Zadno-Azizi teaches an apparatus wherein the struts of the retainer region form a plurality of zig-zags in the expanded state, each zig-zag having a proximal point and a distal point with a strut extending therebetween, each linking strut being connected to one of the distal points (**see figures 2 and 13**).

31. As to **claim 42**, Zadno-Azizi teaches an apparatus wherein the retainer region is self-expanding from the contracted state to the expanded state (**see figure 2; column 3 lines 1-25**).

32. As to **claim 46**, Zadno-Azizi teaches an apparatus wherein the valve member has a mouth that is movable between open and closed configurations, and wherein the valve protector comprises a loop extending around the mouth (**see figure 3**).

33. As to **claim 47**, Zadno-Azizi teaches an apparatus wherein the mouth has a pair of lips connected at two corners, the loop extending from one corner to the other corner to maintain the distance therebetween (**see figure 3**).

34. As to **claim 49**, Zadno-Azizi teaches an apparatus wherein the membrane covers at least a portion of the valve protector (**see figure 2; column 2 lines 25-40**).

35. As to **claim 51**, Zadno-Azizi teaches an apparatus wherein the valve protector has a first diameter and the frame has a second diameter, the first diameter being smaller than the second diameter (**see figure 2**).

36. As to **claim 55**, Zadno-Azizi teaches an apparatus wherein the retention prong is fixed to the strut of the frame (**see column 3 lines 1-25**).

37. As to **claim 59**, Zadno-Azizi teaches an apparatus wherein the retention prong is configured to project radially outwardly in the expanded state (**see column 3 lines 1-25**).

38. As to **claim 62**, Zadno-Azizi teaches an apparatus wherein the membrane encapsulates the struts (**see figure 2**).

39. As to **claim 63**, Zadno-Azizi teaches an apparatus wherein the membrane is positioned on top of the struts (**see figure 2**).

40. As to **claim 64**, Zadno-Azizi teaches an apparatus wherein the membrane is expandable and collapsible with the frame (**see figure 2 and 13; column 3 lines 1-25**).

41. As to **claim 65**, Zadno-Azizi teaches an apparatus wherein the membrane is elastic (**see column 2 lines 25-40**).

42. As to **claim 67**, Zadno-Azizi teaches an apparatus wherein the frame forms a seal with the interior wall of the bronchial passageway (**see summary of invention**).

43. As to **claim 68**, Zadno-Azizi teaches an apparatus wherein the membrane forms a seal with the interior wall of the bronchial passageway (**see summary of invention**).

44. As to **claim 69**, Zadno-Azizi teaches an apparatus wherein the both the frame and the membrane forms a seal with the interior wall of the bronchial passageway (**see summary of invention**).

Claim Rejections - 35 USC § 103

45. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

46. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

47. Claims **5, 24, 32, 33, 52, 53 and 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (US 5,954,766).

48. **As to claims 5 and 53**, Zadno-Azizi substantially discloses the claimed invention; see rejection of claims 1 and 45 above, but does not disclose the frame comprising a super-elastic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi's invention by providing a frame that comprises a super-elastic material so that it can be easily placed within the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

49. **As to claim 24**, Zadno-Azizi substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the valve protector region and the retainer region being composed of metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi's invention by providing a valve protector region and a retainer region being composed of metal so that it provides a stronger gripping means, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

***In re Leshin*, 125 USPQ 416.**

50. **As to claims 32, 33 and 52**, Zadno-Azizi substantially discloses the claimed invention; see rejection of claims 1 and 45 above, but does not disclose the linking struts, retainer region and valve protector region that are formed of the same material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi's invention by providing the linking struts, retainer region and valve protector region that are formed of the same material in order to prevent corrosion due to material differences, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. ***In re Leshin*, 125 USPQ 416.**

51. **As to claim 61**, Zadno-Azizi substantially discloses the claimed invention; see rejection of claim 60 above, but does not disclose a membrane that has a thickness of about 0.001-0.010 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi's invention by providing a membrane that has a thickness of about 0.001-0.010 inches so that it fits properly within the patient, since it has been

held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

52. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (US 5,954,766) in view of Deem et al. (US 6,679,264).

53. As to claim 10, Zadno-Azizi substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a valve member that comprises lips of the mouth being curved. Deem discloses an apparatus that does provide a valve member that comprises lips of the mouth being curve (see figure 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi invention by providing a valve member that comprises lips of the mouth being curved as taught by Deem in order to provide a smoother fluid flow.

54. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (US 5,954,766) in view of Reich (US 4,846,836).

55. As to claim 20, Zadno-Azizi substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a valve protector region that is rigid. Reich teaches an apparatus that does provide a valve protector region 23, 24, 31 and 32 (see column 7 lines 25-35) that is rigid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zadno-Azizi invention by providing a valve protector region that is rigid as taught by Reich so that the valve member is protected.

Claim Rejections - 35 USC § 112

56. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

57. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: In reference to claim 8, the applicant has disclosed intended use of but does not claim that the duckbill valve includes a small channel opening that allows flow in both directions.

Allowable Subject Matter

58. Claims 16, 18, 38-41, 43, 44, 48, 50 and 56--58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest a valve member blocking fluid flow in both an inhalation direction and in an exhalation direction; wherein the tube has at least one window formed therein; and wherein valve protector region comprises a plurality of struts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Art Unit 3772


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